MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
MASSACHUSETTS IMMUNIZATION PROGRAM (MIP)

GENERAL PROTOCOLS FOR STANDING ORDERS

I. Requirements for Administration of All Vaccines

A. Persons Administering Vaccines

1. Health care providers who administer vaccine must have the legal authority to do so and shall be directly accountable for the safe and effective administration of immunizing agents. Furthermore, they must be appropriately trained in all aspects of vaccine administration including:
   a. Proper storage and handling of vaccines;
   b. Information to be elicited from patient or parent/legal representative before vaccination;
   c. Information to be given to patient or parent/legal representative before vaccination;
   d. Techniques for vaccine administration; and
   e. Ability to handle adverse reactions.

2. Health care providers who administer vaccine should have evidence of immunity or be immunized against measles, mumps, rubella, varicella, hepatitis B, influenza, tetanus and diphtheria.

B. Screening Patients Prior to Vaccination

1. Screen for patient for eligibility for vaccination. Eligibility is based on:
   a. The patient's age;
   b. The patient's vaccination status (eg. persons previously unvaccinated or due for vaccination according to the recommended schedule); and
   c. The presence of a medical condition that puts them at high risk.

2. Screen for contraindications:

   a. At minimum, obtain information regarding vaccines previously received, preexisting health conditions, allergies, and adverse events that occurred after previous vaccinations.
   b. Physical examination and vital signs (i.e., temperature, blood pressure, pulse, respirations) measurement are not necessary before or after administration of vaccines, unless specifically indicated.
   c. Assessment of patient's physical condition can be based exclusively on information elicited from the patient, parent or guardian and on the provider's observations of the patient's condition.
   c. Anyone for whom vaccine is deferred because of a contraindication should be referred to their primary care provider for evaluation and confirmation of the contraindication.

3. Latex allergies

   Dry natural rubber is used in syringe plungers and vial stoppers. Dry natural rubber and natural rubber latex contain the same impurities (e.g., plant proteins and peptides) believed to be responsible for allergic reactions, but in lesser amounts than latex. Allergic reactions (including anaphylaxis) after vaccination procedures are rare. Only one report of an allergic reaction after administering hepatitis B vaccine in a patient with known severe allergy (anaphylaxis) to latex has been published (Lear; Lancet, 1995).

   A person with a history of an anaphylactic reaction to latex should be referred to a health care provider for evaluation and safe administration of vaccines. For latex allergies other than anaphylactic allergies (e.g., history

of contact allergy to latex gloves), vaccines supplied in vials that contains dry natural rubber or natural rubber latex can be administered.

For additional information, refer to Attachment I, which is current as of July 15, 2004. For the most up-to-date information, please refer to package inserts or visit http://www.vaccinesafety.edu/package_inserts.htm.

C. Patient Education Requirement

1. Provide patient, parent or legal representative with adequate information regarding the risks and benefits of a vaccine, and answer any questions. CDC-developed Vaccine Information Statements (VISs), which provide this information, must be used for all vaccines for which they have been developed (42 U.S.C. Section 300aa-26). The most current version of the appropriate VIS **must** be used for **each dose** of vaccine administered. Each patient, or the parent/legal representative, must receive a copy of the form prior to administration of the vaccine. Copies of the most recent VISs are available at your Massachusetts Immunization Program (MIP) regional office or local vaccine distributor. They are also available on the CDC website: www.cdc.gov/nip/publications/VIS. Provide non-English speakers with a VIS in their own language, if available. VIS's in many languages for all vaccines are available at www.immunize.org/vis.

2. Appropriate materials and information may be substituted **only** if VISs are unavailable. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood.

3. Address questions and concerns posed by the patient or parent/legal representative.

4. Obtaining a signature from the patient or parent/legal representative is **not** required. However, you may still obtain one if you wish.

5. Record any patient refusals or medical contraindications.

D. Consent and Education Requirements When Parent or Legal Representative Not Present

1. While there is no federal requirement for a signature to be obtained prior to immunization, state law generally requires the consent of a parent or legal representative regarding the treatment of minors, if the parent or legal representative is not present. However, there are federal policies relating to signatures acknowledging receipt of the Vaccine Information Statements (VISs), which must be part of the consent process.

   In school-based programs, or other programs where the parent or legal representative is not likely to be present at the time of immunization, the parent or legal representative may **either**:
   a. Sign an individual consent form for the administration of each dose of vaccine, which includes acknowledging receipt of the VIS prior to each dose; **or**
   b. Sign a single consent form for the administration of an entire vaccine series (e.g. hepatitis B vaccine), if permissible by the institution's legal counsel. Single signature consent forms must:
      (i) Demonstrate that the parent/legal representative acknowledges the receipt of the VIS and gives permission for their child to be vaccinated with the complete series.
      (ii) Describe the future process whereby the VIS shall be sent home prior to each subsequent dose.
      (iii) Describe a future process whereby a "Withdrawal of Permission Form" will be sent home prior to each subsequent dose. This statement notifies the parent or legal representative that, based on their earlier permission, the next dose will be given (list the date), unless the parent or legal representative signs the "Withdrawal of Permission Form".

2. Establish procedures for responding to questions from parent or legal representative by telephone or mail.

3. In the patient's medical record, maintain the original consent signature(s), any "Withdrawal of Permission Forms", and dates the VISs were sent home to the parent or legal representative.

4. Consult with the institution's legal counsel about any policies or requirements specific to the institution regarding consent and consent forms.

5. For additional information, please see the MIP's Guidelines for School-Based Hepatitis B Immunization Initiative, October 1999.

E. Vaccine Storage and Handling

1. Store all vaccines, with the exception of live attenuated influenza vaccine (LAIV) and varicella vaccine, in a refrigerator at 2ºC to 8ºC (35ºF to 46ºF). Store LAIV and varicella vaccine in a freezer at ≤ -15ºC (≤ 5ºF). Maintain a log (available from the MIP) of daily temperatures recorded twice daily (AM and PM) for all vaccine storage units. Vaccines should **not** be stored on the refrigerator or freezer door.

Note:

- If varicella vaccine is stored at refrigerator temperature (2-8ºC or 36-46ºF) prior to reconstitution, it must be used within 72 hours of refrigeration. Varicella vaccine stored at refrigerator temperature which is not used within 72 hours must be discarded.
- If LAIV is thawed at refrigerator temperature (2-8ºC or 36-46ºF), it must be used within 24 hours of refrigeration. LAIV stored at refrigerator temperature which is not used within 24 hours must be discarded.

2. Multi-dose vials that contain a bacteriostatic agent, usually thimerosal, can be used until the date of expiration once they are opened, unless the vial becomes visibly contaminated or is not stored at the correct temperature. Label opened multi-dose vials with the date and time it was opened. However, Menomune (meningococcal polysaccaride vaccine) must be discarded 35 days after reconstitution.

3. Store vaccines separate from other medication and biologics. Do not store food or beverages in the same refrigerator or freezer as vaccines.

F. General Administration Guidelines

1. Administer immunization(s) **per the vaccine-specific standing order**, developed in accordance with the Recommendations of the Advisory Committee on Immunization Practices (ACIP), other national advisory documents, and vaccine package insert(s). Remember to always read the vaccine package insert(s) prior to administration.

2. Hands should be washed before each new patient is immunized. Alcohol-based hand rubs or gels may be used. Gloves are **not** required when administering vaccines unless there is potential for exposure to blood and body fluids, the health care provider has open hand lesions.

3. Syringes and needles must be sterile and preferably disposable, to minimize the chances of contamination. Changing needles between drawing up the vaccine into the syringe and injecting it is not necessary, unless indicated in the package insert. After use, needles should not be recapped, detached, bent, cut, or broken. Used needles and syringes should be disposed of as medical waste in specially labeled puncture-proof "sharps" containers to prevent accidental inoculation or theft. A separate needle and syringe should be used for each injection. Different vaccines should not be mixed in the same syringe unless specifically licensed and labeled for such use.

Occupational Safety and Health Administration (OSHA) Regulations:
In order to reduce the incidence of needle-stick injuries among healthcare workers and the consequent risk for bloodborne diseases acquired from patients, federal regulations now require that safer injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for parenteral vaccination in all clinical settings when such devices are appropriate, commercially available, and capable of achieving the intended clinical purpose. Additional information is available on the OSHA website: www.osha.gov.

4. The person who prepares the vaccination should be the same person who administers the vaccination. Pre-drawing of immunizations in a non-mass vaccination clinic setting (e.g., provider office) is discouraged. If syringes are pre-filled in a non-mass vaccination clinic setting, they should be stored in the refrigerator, used on the same day they are filled, and they should be labeled for identification purposes.
   MMR, varicella, and yellow fever vaccines should be stored in their boxes until they are ready to use, and they should **never** be drawn up ahead of time.

5. Although certain vaccination specialists advocate aspiration, no data exist to document the necessity for this procedure. If aspiration results in blood in the needle hub, remove and discard the syringe. Begin the vaccination procedure again.

6. A brief period of bleeding at the injection site is common and can usually be controlled by applying gentle pressure for several minutes. Use of adhesive bandages on an injection site for more than 1 or 2 hours can mask an infection and is discouraged.

7. Personnel administering vaccines should consider using methods for alleviating patients' discomfort and pain associated with vaccination. The Advisory Committee on Immunization Practices (ACIP) suggests comfort measures and distraction techniques for children, topical analgesics, and oral nonaspirin analgesics.

8. Whenever possible, patients should be observed for an allergic reaction for 15 to 20 minutes after receiving immunizations. Facilities and personnel should be available to treat immediate hypersensitivity reactions. For additional information, please see the MIP's *Standing Orders for Emergency Treatment.*

G. Documentation Requirements

1. Document the following information in the patient's permanent record is **required** for each dose of vaccine administered:
   a. Patient's name,
   b. Patient's age,
   c. Type of vaccine,
   d. Dose of vaccine,
   e. Site and route of administration,
   f. Date of administration of vaccine,*
   g. Manufacturer and lot number of vaccine,*
   h. Name and address of health care provider administering the vaccine (the address should be the address where the record is kept),*
   i. Date printed on the Vaccine Information Statement (VIS),*
   j. Date the VIS is given to the patient, or the patient's parent or legal representative,*

   * Required by the National Childhood Vaccine Injury Act of 1986

   If relevant, also record:
   i) Any preexisting medical conditions,
   ii) Date next dose is due.

2. Requirements for retention of written documentation vary and depend on licensing specifications. Clinics and hospitals **must** retain written documentation for a period of *30 years* after the discharge or final treatment of the patient (105 CMR:140.302C, 105 CMR:130.370A, MGL c111, s70). All other facilities, e.g., doctors' offices, BOHs, VNAs, nursing homes, etc., **must** retain documentation for a period of *10 years* following the end of the last calendar year in which the documentation occurred (NCVIA 1986).

3. Provide the patient or parent/legal representative with a vaccine card documenting the vaccines given and the date the next doses are due.

H. Post-Vaccination Adverse Event Reporting Requirements

1. Any post-vaccination adverse event(s) **must** be reported to the Vaccine Adverse Event Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available. Report all clinically significant events to the Vaccine Adverse Event Reporting System (VAERS), regardless of whether or not you believe the events are caused by the vaccine. Public clinics, that are sponsored by boards of health or Visiting Nursing Associations, should report adverse events to the Massachusetts Immunization Program, 617-983-6800. Private providers should forward their report to the ERC Bioservices Corporation using VAERS forms or call 1-800-822-7967. Providers can now submit VAERS reports via the internet at: www.vaers.org.

   In addition, report any post-vaccination adverse event to the patient's primary care provider or their local board of health (if no such provider is identified). Also, encourage patients or their parents/legal representatives to report any post-vaccination adverse event that occurs after they leave your facility to their primary care provider or their local board of health (if no such provider is identified).

2. Provide the patient's primary care provider or local board of health (if no such provider can be identified) with a record of the relevant information about the immunization(s) given, including any adverse events.

3. Encourage patients or parents/guardians to inform their primary care provider or their local board of health (if no such provider can be identified) of any adverse event(s) following immunization after they leave your facility.

4. The patient or the parent/legal representative should be informed of the importance of having a medical home (i.e. primary care provider) and receiving other preventive medical services.

I. Additional Documentation Requirements for Mass Immunization Clinics

1. Keep a registration sheet for patients attending each clinic. Include name, address or department, telephone number, appointment time, age and date of clinic.

4. Establish a system for central storage of all documentation relating to vaccine administration. This will include any tear off sheets, vaccine administration records or registration sheets.

3. If more than one type of vaccine is administered to a patient, a separate vaccine administration record **must** be used for each type of vaccine.

II. Recommendations for Drawing Up Vaccine

When drawing up vaccine in preparation for mass immunization clinics or clinical sessions, three issues must be considered:

1. Viability of the vaccine;

2. Ability to identify the vaccine in the syringes; and
3. Avoiding vaccine wastage.

1. Viability of vaccine

a. Vaccines should be drawn up as close to the time of administration as possible. Once the vaccine is drawn up, it should be placed in the refrigerator or in containers with cold packs. The CDC recommends that MMR, varicella, and yellow fever vaccines should **never** be drawn up ahead of time.

b. Environmental conditions, such as heat and light, can affect the viability of the vaccines, and vaccines vary as to their stability.
In order to ensure the viability of vaccines, there are specific restrictions regarding MMR, varicella, yellow fever, and Tripedia®-ActHIB® [TriHIBIT®] vaccines:
(i) **Varicella vaccine** must be used ≤ 30 minutes after reconstitution, or be discarded.
(ii) **ActHIB® vaccine** must be used ≤ 24 hours after reconstitution, or be discarded.
(iii) **Tripedia®-ActHIB® [TriHIBIT®] vaccine** must be used ≤ 30 minutes after reconstitution, or be discarded.
(iv) **Yellow fever vaccine** must be used ≤ 1 hour after reconstitution, or be discarded.
(v) **Tripedia®** must be used ≤ 8 hours after reconstitution with saline, or be discarded.
(vi) **MMR vaccine** should be used as soon as possible after reconstitution. MMR vaccine not used ≤ 8 hours after being reconstituted must be discarded. Cold (refrigerated) diluent should be used to reconstitute MMR vaccine that will not be used immediately. Vials and syringes with MMR vaccine should be protected from light at all times.

b. If there are any questions about the viability of a vaccine, consult your regional immunization nurse, or the vaccine manufacturer. Mishandled or expired vaccine administered should not be counted as valid doses. The only exception is those antigens with serologic correlates of immunity (i.e., measles, mumps, rubella, varicella, hepatitis B, hepatitis A, *Haemophilus influenzae* type b, diphtheria, and tetanus).

2. Ability to identify vaccine in the syringes
In order to reduce the risk of medication administration errors, the CDC strongly discourages pre-filling syringes. In situations where pre-filling syringes is inevitable, medication administration errors may be avoided by:
a. Storing syringes with vaccines of the same type and same lot number in separate or divided containers or trays.
b. Label each syringe with:
(i) type of vaccine;
(ii) lot number;
(iii) date and time vaccine was drawn up;
(iv) initials of the person who drew up the vaccine.
c. Label each container or tray with:
(i) type of vaccine;
(ii) date and time vaccine was drawn up;
(iii) initials of the person who drew up the vaccine.
d. Syringes other than those filled by manufacturer **must** be discarded at the end of the day.

3. Avoiding vaccine wastage

In order to avoid wastage:
a. Do not draw up more vaccine than will be used at the clinic or session.

b. Ensure the cold chain is maintained until the vaccine is administered.
d. Adhere to sterile technique when drawing up the vaccine.

References

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CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Advisory Committee on Immunization Practice (ACIP). MMWR 1991;40(No. RR-13):1-25.

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CDC. Update: recommendations to prevent hepatitis B virus transmission – United States. MMWR 1994;44:574-575.

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CDC. Using live, attenuated influenza vaccine for prevention and control of influenza: Supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2003;52(RR13):1-8.

Other References

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Vaccine	Brand Name	Manufacturer	Packaging	Contains Dry Natural Rubber[1,2]	Contains Thimerosal as a Preservative
Anthrax	Biothrax	BioPort	Multi dose vial	Yes	No
DT	DT	Aventis Pasteur	Multi dose vial	Yes	Yes (25mcg/0.5ml)
DT	**DT**	**Aventis Pasteur**	**Single dose vial**	**Yes**	**No (< 0.3mcg/0.5ml)[3]**
DTaP	Infanrix	SmithKline	Vial	No	No
DTaP	**Tripedia**	**Aventis**	**Vial**	**Yes**	**No (< 0.3mcg/0.5ml)[3]**
DTaP	DAPTACEL	Aventis	Vial	Yes	No
DTaP-Hep B-IPV	**Pediarix**	**SmithKline**	**Vial**	**No**	**No(<0.0125mcg/0.5ml)[3]**
DTaP-Hep B-IPV	Pediarix	SmithKline	Syringe	Yes	No(<0.0125mcg/0.5ml)[3]
DTaP-Hib	TriHIBit	Aventis	Vial	Yes	No (< 0.3mcg/0.5ml)[3]
e-IPV	**IPOL**	**Aventis**	**Vial**	**No**	**No**
Hep. A (pedi/adult)	**Havrix**	**SmithKline**	**Vial**	**No**	**No**
Hep. A (pedi/adult)	Havrix	SmithKline	Syringe	Yes	No
Hep. A (pedi/adult)	VAQTA	Merck	Vial	Yes	No
Hep. A (pedi/adult)	VAQTA	Merck	Syringe	Yes	No
Hep. B (pedi/adult)	Engerix	SmithKline	Vial	No	No (< 0.5mcg/0.5ml)[3]
Hep. B (pedi/adult)	Engerix	SmithKline	Syringe	Yes	No (< 0.5mcg/0.5ml)[3]
Hep. B (pedi/adult)	**Recombivax**	**Merck**	**Vial**	**Yes**	**No**
Hep. B-Hib	Comvax	Merck	Vial	Yes	No
HepA & B	Twinrix	Glaxo/SmithKline	Vial	No	No
HepA & B	Twinrix	Glaxo/SmithKline	Syringe	Yes	No
Hib	**ActHIB**	**Aventis**	**Vial**	**No**	**No**
Diluent for Hib	**ActHIB**	**Aventis**	**Vial**	**Yes**	**No**
Hib	PedvaxHIB	Merck	Vial	Yes	No
Influenza	**Fluzone**	**Aventis**	**Vial**	**Yes**	**Yes (25mcg/0.5ml)**
Influenza	Fluzone	Aventis	Syringe	No	Yes (25mcg/0.5ml)
Influenza[4] (0.25ml pedi)	Fluzone	Aventis	Syringe	No	No (< 0.5mcg/0.25ml)[3]
Influenza	**Fluvirin**	**Chiron**	**Vial**	**No**	**Yes (25mcg/0.5ml)**
Influenza	Fluvirin	Chiron	Syringe	No	No (< 1.0mcg/0.5ml)[3]
Influenza	FluMist	Wyeth	Nasal Sprayer	No	No
Japanese Encephalitis	JE-VAX	Aventis	Single/Multi dose vial	No	Yes(17.5mcg/0.5ml)
Meningococcal	Menomune	Aventis	Single dose vial	Yes	No
Meningococcal	Menomune	Aventis	Multi dose vial	Yes	Yes (25mcg/0.5ml)
MMR	**MMRII**	**Merck**	**Vial**	**No**	**No**
Diluent for MMR	**MMRII**	**Merck**	**Vial**	**No**	**No**
PCV7	**Prevnar**	**Wyeth**	**Vial**	**Yes**	**No**
PPV23	**Pneumovax**	**Merck**	**Vial**	**No**	**No**
Rabies	IMOVAX	Aventis	Vial	No	No
Rabies	IMOVAX	Aventis	Syringe	Yes	No
Rabies	RabAvert	Chiron	Vial	No	No
Smallpox	Dryvax	Wyeth	Vial	Yes	No
Diluent for Smallpox	Dryvax	Wyeth	Syringe	N/A	No
Td	Td	Aventis	Vial	Yes	Yes (25mcg/0.5ml)
Td	**Td**	**UMass Biologics**	**Vial**	**Yes**	Yes (8.26mcg/0.5ml)
Typhoid(oral)	Vivitef Berna	Berna	Capsule	No	No
Typhoid (injectable)	TyphimVi	Aventis	Vial	No	No
Typhoid (injectable)	TyphimVi	Aventis	Syringe	Yes	No
Varicella	**Varivax**	**Merck**	**Vial**	**No**	**No**
Diluent for Varicella	**Varivax**	**Merck**	**Vial**	**No**	**No**
Yellow Fever	YF-Vax	Aventis	Vial	Yes	No
Hepatitis B IG	Bay Hep B	Bayer	Vial	Yes	No
Hepatitis B IG	Nabi-HB	Nabi	Vial	No	No
Human IG	Gammagard	Baxter	Vial	No	No
Human IG	Gammagard Diluent	Baxter	Vial	Yes	No
Human IG	**Immune Globulin**	**UMass Biologics**	**Vial**	**Yes**	**No**
Rabies IG	Imogam Rabies	Aventis	Vial	No	No
Rabies IG	Bayrab	Bayer	Vial	Yes	No
Tetanus IG	Bay Tet	Bayer	Vial	Yes	No
Varicella Zoster IG	**VZIG**	**UMass Biologics**	**Vial**	**Yes**	**No**

1 Yes = Contains dry natural rubber in some part of the vaccine packaging. Very few documented sensitization reactions have been attributed to dry natural rubber products, which contain fewer antigenic proteins than latex. There has been only 1 published report of an allergic reaction after vaccination in a patient with known severe allergy(anaphylaxis) to latex (Lear. Lancet 1995;345:1249).
2 No = Does not contain dry natural rubber, natural rubber latex, or any other latex-containing products.
3 This vaccine contains only trace amounts of mercury introduced during the manufacturing process. This amount is so small that CDC classifies these vaccines as no longer containing thimerosal as a preservative. (CDC. MMWR 2000;49:642,651)
4 A limited supply of the preservative free formulation of Fluzone vaccine is manufactured each year.
*** Bolded vaccines are those currently distributed by MIP.**
[Please note: This information is current as of July 15, 2004. For the most up-to-date information, please refer to package inserts or visit http://www.vaccinesafety.edu/package_inserts.htm]